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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/501,819	10/27/2004	Sunita Chauhan	NAY 0005 PA	5096	
23568 7590 0921/2008 DINSMORE & SHOHL LLP ONE DAYTON CENTRE, ONE SOUTH MAIN STREET SUITE 1300 DAYTON, OH 45402-2023			EXAM	EXAMINER	
			ROZANSKI, MICHAEL T		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/501.819 CHAUHAN ET AL. Office Action Summary Examiner Art Unit Michael Rozanski 3768 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 04 December 2007. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-12.14-23.27 and 28 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-12,14-23,27 and 28 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

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#### DETAILED ACTION

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-7, 9-12, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rolt et al (US 5,501,655) in view of Noske et al (US 4,836,191).

Rolt et al disclose a method for use during ultrasonic treatment of a cancer in subject tissue (col 5, lines 40-49), including two ultrasonic probes 100, 102 (col 6, line 55; see figure 4), wherein the invention is not limited to only two probes (col 6, lines 4-23). Each probe is mounted on a positioning mechanism, one mounted on a six degree-of-freedom motorized computer controlled platform, and the other mounted on a five degree-of-freedom manually controlled platform (col 7, lines 16-30). Rolt et al also disclose a processor that generates timing and control signals for activating the signal generators 34 and 36 (col 4, lines 34-49).

However, Rolt et al do not give specific description of the positioning system. Noske et al teach of a shockwave (similar to ultrasonic) system with two probes 3, 4 each with a jig assembly including a central shaft (comprising elements 7 and 8), a plurality of collars (see unlabeled circular element

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connecting elements 5 and 6 to element 7) each mounted on and independently rotatable about or with respect to the central shaft, and a plurality of adjustable supports (elements 5 and 6) each attached to one of the collars to direct waves toward a con-focal point (see figure 1). It would have been obvious to the skilled artisan to modify Rolt et al to have a robotically controlled multi-probe assembly with central shaft, collars, and supports as taught by Noske et al, because this would allow an especially versatile adjustment of a shockwave generator (col 1, lines 47-54).

Furthermore, it would have been obvious to the skilled artisan to make the adjustments automatically controlled due in part to the computer controlled probe platform of Rolt et al, and because it is well settled that it is not "invention" to broadly provide a mechanical or automatic means to replace manual activity which has accomplished the same result. In re Venner, 120 USPQ 192.

Claims **4-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rolt et al (US 5,501,655) and Noske et al (US 4,836,191) as applied to claim 1 in further view of Burdette (US 5,549,638).

Rolt et al and Noske et al do not disclose determining the target tumor by ultrasound (i.e. identification probe) or producing a 3D representation of the portion of tissue. In the same field of endeavor, Burdette teaches of a transducer array 32 whereby pulse echo data is collected and sent to a contour monitoring subsystem 33 that converts the data into a 3D image of the treatment region (col. 5. lines 9-35). It would have been obvious to one with ordinary skill in the art at

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the time the invention was made to modify the probe assembly of Rolt/Noske which is not limited to only two probes (see col 6, lines 4-7 of Rolt et al), to incorporate an additional probe as taught by Burdette, in order to enable enhanced viewing of the treatment region.

Claims 14-23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rolt et al (US 5,501,655) and Noske et al (US 4,836,191) in further view of Burdette (US 5,549,638).

Rolt et al disclose a method for use during ultrasonic treatment of a cancer in subject tissue (col 5, lines 40-49), including two ultrasonic probes 100, 102 (col 6, line 55; see figure 4), wherein the invention is not limited to only two probes (col 6, lines 4-23). Each probe is mounted on a positioning mechanism, one mounted on a six degree-of-freedom motorized computer controlled platform, and the other mounted on a five degree-of-freedom manually controlled platform (col 7, lines 16-30). Rolt et al also disclose processor that generates timing and control signals for activating the signal generators 34 and 36 (col 4, lines 34-49).

However, Rolt et al do not give specific description of the positioning system. Noske et al teach of a shockwave (similar to ultrasonic) system with two probes 3, 4 each with a jig assembly including a central shaft, a plurality of collars each mounted on and independently rotatable about the central shaft, and a plurality of adjustable supports each attached to one of the collars to direct waves toward a con-focal point (see figure 1). It would have been obvious to the skilled artisan to have a robotically controlled multi-probe assembly with central

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shaft, collars, and supports as taught by Noske et al, because this would allow an especially versatile adjustment of a shockwave generator (col 1, lines 47-54).

Furthermore, it would have been obvious to the skilled artisan to make the adjustments automatically controlled due in part to the computer controlled probe platform of Rolt et al, and because it is well settled that it is not "invention" to broadly provide a mechanical or automatic means to replace manual activity which has accomplished the same result. In re Venner, 120 USPQ 192.

Rolt et al and Noske et al do not disclose determining the target tumor by ultrasound (i.e. identification probe) or producing a 3D representation of the portion of tissue. In the same field of endeavor, Burdette teaches of a transducer array 32 whereby pulse echo data is collected and sent to a contour monitoring subsystem 33 that converts the data into a 3D image of the treatment region (col. 5, lines 9-35). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the probe assembly of Rolt/Noske which is not limited to only two probes (see col 6, lines 4-7 of Rolt et al), to incorporate an additional probe as taught by Burdette, in order to enable enhanced viewing of the treatment region.

## Response to Arguments

Applicant's arguments with respect to claims 1-7, 8-12, 14-23, and 27-28 have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/ Primary Examiner, Art Unit 3768

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